

REMARKS

This supplemental response corrects Claim 1 to properly reflect the previous version of claims filed on November 10, 2010. In particular, lines 15-16 of Claim 1 presented here now contains “~~wherein the agent capable of raising an immune response in a dog against a *Chlamydomydia* comprises inactivated or attenuated.~~” No other changes have been made to the claims.

The following Remarks are identical to the Remarks in the Response to Office Action filed on April 7, 2011:

Claims 1, 8-19 and Claim 64 are presently pending. Of these, Claims 16-19 are withdrawn from consideration. Amendments to Claim 1 are discussed below. Support for new Claim 64 is found in original Claim 1. No new matter has been added herewith. The following addresses the substance of the Office Action.

Obviousness

Mackenzie et al. in view of Senyk et al. and Hymas et al.

Claims 1 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mackenzie et al. (EP 0415794A1) Senyk et al. (1980 *Medical Microbiology Immunology* **168**:91-101) and Hymas et al. (U.S. Patent Application No. 2002 0150593). The Examiner concluded that it would have been *prima facie* obvious to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al. and Senyk et al.

Referring to the specification as filed at page 3, third paragraph, the Applicant has made the novel finding of an association between *Streptococcus equi sub species zooepidemicus* (see Example 1), *Mycoplasma cynos* (see Example 2), and a *Chlamydomydia* (see Example 3). In particular, these bacterial species were specifically shown by the Applicant to be associated in connection with Canine Infectious Respiratory Disease (CIRD). In accordance with this specific association, the Applicant has amended Claim 1 to emphasize that the presently claimed compositions comprise the specific combination of: (a) a first agent capable of raising an immune response against *M. cynos* in a dog, and (b) a second agent capable of raising an immune response against either *S. zooepidemicus* or a *Chlamydomydia* species in a dog. New Claim 64 specifies an immunogenic composition that comprises all three of: (a) an agent capable of raising an immune

response against *M. cynos* in a dog; (b) an agent capable of raising an immune response against *S. zooepidemicus* in a dog; and (c) an agent capable of raising an immune response against a *Chlamydophila* in a dog. Only knowledge of a specific connection between these three agents would have led one of ordinary skill in the art to combine them into a single composition. However, such an association between these specific bacteria was not known until the present disclosure.

Referring to the specification as filed at page 1, paragraphs 3-5, the prior art taught that infectious agents previously considered to be the major causative pathogens of CIRD were canine parainfluenzavirus (CPIV), canine adenovirus type 2 (CAV-2), and canine herpesvirus (CHV), canine respiratory coronavirus (CRCV) and the bacterium *Bordetella bronchiseptica* (*B. bronchiseptica*). These viruses and bacterium were frequently isolated during outbreaks in dogs and were shown to cause respiratory symptoms or lung lesions in experimental infections. Also, human reovirus and mycoplasma species were isolated from dogs with symptoms of CIRD. Referring to page 3, third paragraph of the present specification, all of the dogs in the Applicant's study were vaccinated against CPIV and CAV-2, two of the leading agents believed to be involved in the etiology of CIRD. Accordingly, the Applicant has shown that CIRD can be caused in the absence of these viruses.

Given the teachings of the prior art, one of ordinary skill in the art may have combined one or more of CPIV, CAV-2, CHV, CRCV and *B. bronchiseptica*, but of the thousands of known microorganisms and the virtually countless number of combinations of microorganisms, there was no reason for one of ordinary skill in the art to develop the presently claimed combination of *Mycoplasma cynos*, *Streptococcus equi sub species zooepidemicus* and/or *Chlamydophila* in a single immunogenic composition. Applicant respectfully asserts that the Examiner has failed to articulate a reason with rational underpinning to support the proposed combination. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness") (cited with approval in KSR, 550 U.S. at 419).

Until the present disclosure, there was never a known connection between CIRD and *Mycoplasma cynos*, *Streptococcus equi sub species zooepidemicus* and/or *Chlamydophila* species. Accordingly, there was no reason for one of ordinary skill in the art to formulate the

presently claimed compositions, which specifically comprise a first agent capable of raising an immune response against *M. cynos* and a second agent capable of raising an immune response against either *S. zooepidemicus* or a *Chlamydophila* species. Claims 8-15 ultimately depend from Claim 1. Accordingly, all of the presently claimed compositions are not *prima facie* obvious in view of the cited combination of references and the Applicant respectfully requests that the rejection be withdrawn.

Additional Rejections under 35 U.S.C. § 103(a)

1. Claims 1 and 8 were rejected as being unpatentable over Mackenzie et al. (*supra*) Jacobs et al. (U.S. Patent No. 6,682,745) and Hymas et al. (*supra*).
2. Claims 1, 8-9, 12 and 15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Senyk et al. (*supra*), Hymas et al. (*supra*) and Hansen et al. (U.S. Patent No. 5,665,363).
3. Claims 1, 8-9, 12 and 15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Jacobs et al. (*supra*), Hymas et al. (*supra*) and Hansen et al. (*supra*).
4. Claims 1, 8-10 and 12-15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Senyk et al. (*supra*), Hymas et al. (*supra*) and Acree et al. (U.S. Patent No. 4,824,785).
5. Claims 1, 8-10 and 12-15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Jacobs et al. (*supra*), Hansen et al. (*supra*), Hymas et al. (*supra*) and Acree et al. (*supra*).
6. Claims 1, 8-10 and 12-15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Senyk et al. (*supra*), Hymas et al. (*supra*) and Brown et al. (U.S. Patent No. 5,661,006).
7. Claims 1, 8-9, 11-12 and 15 were rejected as being unpatentable over Mackenzie et al. (*supra*) Jacobs et al. (*supra*), Hansen et al. (*supra*), Hymas et al. (*supra*) and Brown et al. (*supra*).

In view of the remarks above in connection with the rejection under 35 U.S.C. § 103(a) with regard to Mackenzie et al. in view of Senyk et al. and Hymas et al., none of the additional references including Jacobs et al., Hansen et al., Acree et al. and Brown et al. provide any basis for one of skill in the art to develop the presently claimed compositions, which specifically

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comprise a first agent capable of raising an immune response against *M. cynos* and a second agent capable of raising an immune response against either *S. zooepidemicus* or a *Chlamydomphila* species. Accordingly, all of the presently claimed compositions are not *prima facie* obvious in view of the foregoing combinations of cited references and the Applicant respectfully requests that the rejections be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
ERP02.001APC1DV	11/849,931	VACCINE COMPOSITION FOR VACCINATING DOGS AGAINST CANINE INFECTIOUS RESPIRATORY DISEASE (CIRD)	04-Sep-2007
ERP02.001C2	12/816,214	VACCINE COMPOSITION FOR VACCINATING DOGS AGAINST CANINE INFECTIOUS RESPIRATORY DISEASE (CIRD)	15-Jun-2010

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the

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Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 5, 2011

By: /Raymond D. Smith/

Raymond D. Smith
Registration No. 55,634
Agent of Record
Customer No. 20995
(949) 760-0404

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